

Running Head: Uterine Leiomyomas

Symptom severity and quality of life of women with uterine leiomyomas

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Introduction

Uterine leiomyoma are benign smooth muscle tumors within the uterus (Lewis, 2004). Their etiology is unknown and they may cause a number of symptoms including urinary frequency, constipation, dyspareunia, and menorrhagia (Pron et al., (2003). Complications such as miscarriage, dysfunctional labor, Breech births, Cesarean sections and other problems of pregnancy, labor and birth are increased in women with leiomyoma as well (Coronado, Marshall, & Schwartz, 2000). Furthermore, the majority of all hysterectomies, which is the second most performed surgery in the United States, are received by women with uterine leiomyomas (Velebil, Wingo, Xia, Wilcox, & Peterson, 1995). Although uterine leiomyomas are one of the most common gynecological conditions, the condition does not receive much attention from the media or researchers.

Symptom severity and quality of life of women with leiomyomas have been investigated individually and along with other gynecological disorders. Many of these studies focused on the participants' pain and menorrhagia. Few studies have evaluated the severity of symptoms such as bloating, constipation, and urinary frequency, which are unique to women with uterine leiomyomas because they are related to the bulk or placement of the leiomyomas. Thus, the purpose of this study was to evaluate the symptom severity and health-related quality of life of women with uterine leiomyoma using a tool that evaluates common symptoms of the condition. The possible correlation between symptom severity and health-related quality of life was also assessed.

Review of Literature

Prevalence of Leiomyoma in the Population

Results from a study by Velebil et al. (1995), which analyzed data from the National Hospital Discharge Survey from 1988 to 1990, suggest that the average annual rate of uterine leiomyomas was 30.4 per 10,000 women between the ages and 15 and 40, making uterine leiomyomas one of the most frequently diagnosed gynecological disorders. Eighty-three percent of these women had a hysterectomy.

Racial Differences in Rate of Diagnosis

Findings suggest variation in the rate of uterine leiomyoma diagnosis among demographic groups. Marshall et al. (1997) examined the differences in the incidence of uterine leiomyoma among women of various races and age groups. As part of the Nurses' Health Study II cohort, 95,061 premenopausal nurses, age 25-44 with uteri, and no current diagnosis of uterine leiomyomas, were followed to determine the incidence over four years. The incidence rate per 1000 women years among black women (37.9) was significantly greater than rates among white (12.5), Hispanic (14.5) and Asian women (10.4).

Data from the National Hospital Discharge Survey also showed differences among racial groups and the rate of uterine leiomyoma diagnosis. More women of races other than white were discharged with a primary diagnosis of uterine leiomyoma (53.2 per 10,000) compared to white women (24.4 per 10,000). The rate of diagnosis of uterine leiomyomas for women of races other than white was significantly higher than white women in the 30-34, 35-39, and 40-44 age groups. The race or ethnicity was not specified in the women of color group (Velebil et al., 1995).

Racial Differences in Age at Diagnosis

There appears to be strong evidence that there is a difference in the age at diagnosis between racial groups. Kjerulff et al. (1996) examined the differences in incidence of uterine leiomyomas, symptom severity, and age at diagnosis between black and white women hysterectomy patients. The longitudinal study included 301 black and 281 white women whose presurgery diagnosis of uterine leiomyomas was confirmed by surgery. The average age at diagnosis of uterine leiomyomas was 41.6 years for white women and 37.5 years for black women. The 30 to 39 age group included 48% black women and 32% white women. This finding is important because in a previous analysis by Kjerulff, Guzinski, Langenberg, Stolley, Moye, and Kazandjian (1993), black women had higher annual rates for hysterectomies before the age of 40 compared to white women. This may be because black women are more likely to be diagnosed at a younger age. This finding is also supported by Marshall et al. (1997) who found that black women were more frequently diagnosed at a younger age than the white, Hispanic and Asian groups. It is important to note that the incidence of uterine leiomyomas increased with age within all groups in this study.

Racial Differences in Symptom Severity

Findings in Kjerulff's study (1996) also illustrated a great difference in symptom severity between black and white women. A significantly larger percent of black women were more likely to report having very severe or severe pain, constipation and more stomachaches. Anemia, which was defined as a presurgical hematocrit of less than 35%, was found in 56% of black women compared to 38% of white women did.

Pron et al. (2003) also examined the variation of symptoms reported among races in a study including 555 women with uterine leiomyomas undergoing uterine artery embolization. Fibroid related symptoms were categorized into four groups including pelvic pain, pelvic pain with bleeding, bleeding only, and bulk related effects without pain or bleeding. White women with uterine leiomyomas were significantly more likely to report having bulk related symptoms, whereas black women were more likely to report having a combination of pain and bleeding. In addition, black women reported a significantly longer mean duration of years in which they experienced symptoms than white women.

Racial Differences in Hysterectomy Rates

Kjerulff et al. (1993) explored the racial differences in hysterectomy rates. Discharge summaries from 53,159 women with hysterectomies performed in Maryland between 1986 and 1991 were used for the study. The data set included 70% white women, 26% black women, and 3% other races including Hispanic, Asian and Eskimo, but only white and black women were included in the analysis. Primary diagnoses, type of hysterectomy (abdominal, vaginal, or subtotal) patient age, source of payment and complications of surgical and medical care were analyzed.

Black women in Maryland received hysterectomies an average of four years younger than white women (46.1 vs. 42.0). The average annual rate of hysterectomy was higher for black women in all age groups to the age of 49. However, white women had higher rates after the age of 50. Twice as many black women with a primary diagnosis of uterine leiomyoma had hysterectomies than did white women (65.4% vs. 28.5%) (Kjerulff et al., 1993). Black women were also more likely to have abdominal

hysterectomies than white women. This finding is important because having an abdominal hysterectomy was significantly correlated with complications after the procedure. Overall, 19.7% of black women had one or more complications compared to 10% of white women. The average length of stay was significantly longer for black women than white women as. The increased symptom severity of African-American women may explain why they are significantly more likely to receive hysterectomies, in general, and at a younger age.

Effect of symptoms on Psychological Well-being

Rannestad, Eikeland, Helland, and Qvarnstrom (2000) investigated the impact pain has on quality of life and psychological well-being among women with gynecological disorders. The study consisted of 111 women with benign gynecological disorders, including uterine leiomyomas, undergoing hysterectomies. The control group consisted of 173 women of similar age and intact uteri. The Quality of Life Index (QLI) and the McGill Pain questionnaire were used. The psychological/spiritual domain of the QLI was used to determine psychological well-being. Pain had a negative effect on quality of life for both groups, however, the mean scores for participants with gynecological disorders were lower on the overall QLI compared to the control group, regardless of the frequency of pain (Rannestad et al., 2000).

The participants with gynecological disorders also had significantly lower means for the health functioning subscale items of the QLI than the control group. In contrast, there was no significant difference in the psychological/spiritual subscale score indicating that women with gynecological disorders do not differ psychologically from women without these disorders (Rannestad et al., 2000).

Alternatively, findings from a study by Salter (1985) suggest that there is an association between specific symptoms and psychological well-being of women who suffer from gynecological disorders. The study included 102 women who sought treatment for various gynecological disorders. The Anxiety sub-scale from the Kellner-Sheffield self-rating scale of distress measured anxiety while depression was measured with the Zung Depression Scale. Factors such as flooding, clotting, and discomfort during menstrual periods, which were part of the bleeding component, had a positive correlation with depression. Painful periods were positively correlated with the anxiety. This finding is important because women with uterine leiomyoma often suffer from pain and heavy bleeding, so they have a definite risk for developing depression and anxiety.

Symptom Severity of Women with Leiomyoma

Uterine leiomyomas can produce a number of unpleasant symptoms. Pron et al. (2003) evaluated these symptoms, including their severity, in women with uterine leiomyomas. The most frequently reported symptom was heavy bleeding (80%). Anemia from chronic blood loss was a secondary problem for many of these women. Pelvic pain was the second most reported symptom (75%). Sixty-three percent of women reported having a combination of pain and bleeding. Bulk related symptoms caused urinary frequency, back pain, and dyspareunia. Women also reported a limited ability to exercise, but it was not stated if this was related to fatigue, pain, heavy bleeding, or body image disturbance related to the appearance of being pregnant. Forty percent of women reported taking time off work, usually during the menstrual period, because of their symptoms. This finding suggests that many women suffering from leiomyomas may experience an additional financial burden due to missing work as well. Overall, 58% of the participants

reported a fibroid (leiomyoma) impact scale score of 7 on a scale of 0 to 10. This indicates that their symptoms truly interfere with their daily or usual activities (Pron et al., 2003).

The Effects of Symptom Severity on Quality of Life

There appears to be strong evidence that women with leiomyomas have symptoms that negatively affect many aspects of their quality of life. Rowe, Kanouse, Mittman, and Bernstein (1999) conducted a study measuring the association between quality of life and symptoms of common gynecological conditions. The retrospective study was conducted for three years and included 482 women (61% with uterine leiomyomata) who had hysterectomies for benign conditions. The women were placed in four groups, (bleeding, pain, pelvic discomfort, and asymptomatic) based on the principal characteristic of their symptoms. Women with bleeding uterine leiomyomas were placed in the bleeding group. Women with uterine leiomyomas without bleeding were placed in the pelvic discomfort group. It is important to note that the primary pain group did not specifically include women with uterine leiomyomas; however, women with uterine leiomyomas frequently experience dysmenorrhea. The groups were then compared to examine differences in six quality of life scales: role, sexual mood impairment, impairment due to bleeding, change in symptom severity, and general health perception.

The women in the pain group had significantly higher role, sexual and mood impairment and symptom severity than all other groups. The bleeding group had a significantly higher impairment due to bleeding than the three other groups. Overall, the pain group had a significantly higher mean general health perception score (74.4) than the bleeding group (60.7), the pelvic discomfort group (44.1) and the asymptomatic group

(49.4). Higher scores indicate more impairment in all quality of life scales (Rowe et al., 1999).

To illustrate the extent to which gynecological conditions negatively affected quality of life, the mean of the emotional well being scores for each group in the study was compared to the mean emotional well-being score of women with other medical and psychiatric conditions. The mood impairment scale, which measures depression and anxiety, was used to analyze the emotional well being of different populations. Each of the four groups scored significantly worse on the mood impairment scale than women with hypertension, diabetes, heart disease, and arthritis (Rowe et al., 1999).

Carlson, Miller, and Fowler (1994) analyzed the quality of life and symptom severity of women having hysterectomy. The Maine Women's Health Study was a prospective study that analyzed the outcomes of hysterectomy for nonmalignant gynecological disorders. The participants were placed in four groups (leiomyoma, abnormal bleeding, chronic pain or other) depending on their principal diagnosis. The symptom severity of the 418 women was analyzed. The reported symptom severity for women diagnosed with uterine leiomyomas, (about 40% of the participants) before surgery included 43% experiencing bleeding for more than eight days a month, 45% with pelvic pain more than eight days a month, 74% reporting some or a lot of discomfort. Forty-nine percent of the women with leiomyoma had 12 week pregnancy uterus size. Quality of life was measured preoperatively, and at six and twelve months postoperatively, using the Mental Health index, the General Health index and the Activity index. Overall, symptom severity in all groups was significantly improved at six and twelve months after hysterectomy. Additionally, there was a significant improvement in

quality of life scores on all indices for all four groups at six and twelve months after surgery.

Summary

Most studies have analyzed symptom severity and quality of life of gynecological disorders in general. As a result, many of the symptoms that are unique to uterine leiomyoma such as bloating, constipation, urinary frequency and bulk weight gain have not been assessed. There is limited information concerning symptom severity and quality of life of women with uterine leiomyomas. Thus, this study was conducted to determine symptom severity and health-related quality of life of women with uterine leiomyomas using the Uterine Fibroid Symptom and Health Related Quality of Life (UFS-QOL) tool which was developed by Spies et al. (2002).

Methods

The researchers analyzed three research questions: (1) What is the symptom severity for women with uterine leiomyomas? (2) What is the health-related quality of life for women with uterine leiomyomas? (3) How does symptom severity affect the health-related quality of life for these women? The hypothesis was that women with the worst symptom severity would have the lowest quality of life.

Human Subjects Concern

The study was reviewed and approved by the Institutional Review Board. Participation in the study was completely voluntary. An informed consent statement was included with the questionnaire. The participant's right to self-determination was assured since the only questionnaires included in the data collection were returned questionnaires with signed informed consent forms. The purpose of this study, which was to analyze the

symptom severity, quality of life and possible correlation between the two, was explained to the possible participants when they contacted the researcher by email or phone to ensure full disclosure of the study. The participant had the right not to answer any question for any reason. Since some questions might generate emotional distress, the participants were encouraged to contact the researchers if this should happen. The informed consent sheet was separated from the completed questionnaire before any data were analyzed to ensure confidentiality. All completed questionnaires and informed consent forms were locked in a container in a secure office at the Ohio State University College of Nursing.

Participants

The inclusion criteria were premenopausal women over the age of 18 diagnosed with uterine leiomyomas, with intact uteri who had a menstrual cycle in the last 3 months. They had to be able to read and speak English.

Instrument

Symptom severity and health-related quality of life was measured using the Uterine Fibroid Symptom and Health-Related Quality of life questionnaire. Spies et al. (2002) developed the UFS-QOL using 110 women with leiomyomas and 29 normal women not diagnosed with uterine leiomyomas. Symptom severity is measured using 8 items and health-related quality of life is measured using 29 items. There are 6 subscales for health-related quality of life: concern, activities, energy/mood, control, self-consciousness, and sexual function.

Symptom severity, health-related quality of life and each subscale score are transformed into a 0 to 100 point scale. For symptom severity, a score of 0 would

represent no symptom severity, while a score of 100 represents an extreme symptom severity. For health-related quality of life and each subscale, a score of 0 represents no quality of life while a score of 100 represents an optimal quality of life. Hence, a negative correlation would be expected between symptom severity and health-related quality of life.

The UFS-QOL was found to have discriminant validity because women with symptomatic leiomyomas had significantly lower scores for health-related quality of life and significantly higher scores on the symptom severity items, which indicates a lower quality of life and more symptom severity than the non-leiomyoma group. The UFS-QOL was also able to discriminate between women with mild, moderate or severe symptoms of leiomyoma of symptomatic leiomyomas. Test-retest reliability was confirmed by high correlations found between the scores of 27 women on the original questionnaire to scores on the second completion of the same questionnaire (Spies et al., 2002).

Symptom severity and health-related quality of life were also analyzed using single items. Participants rated their symptom severity and health-related quality of life on a 0 to 10 scale. For symptom severity a score of 0 would indicate no symptom severity, while a score of 10 would be extreme symptom severity. For health-related quality of life, a score of 0 would indicate poor health-related quality of life and a score of 10 would represent an optimal quality of life. A negative correlation would be expected for the single items as well.

Procedure

The researcher posted flyers in public places, such as grocery stores, libraries, and shopping malls. Some advertisements were placed in newspapers and websites.

Potential participants contacted the researcher by email or phone. The purpose of the study was explained at that time. If the individual agreed to participate then the researcher asked the participant the following questions: Are you at least 18 years old? Do you still have a uterus? Have you had your period in the last 3 months? Has your physician or nurse practitioner diagnosed you with leiomyomas? If the participant met the criteria the researcher sent the informed consent sheet and the questionnaire to them, with a stamped envelope. Participants completed all items and returned them by mail.

Data Analysis

Descriptive analysis of the demographic data and research questions 1 and 2 was performed. The correlation between symptom severity and quality of life was analyzed using Pearson's r . The alpha level of significance was set at 0.05. The outcome of the hypothesis was tested using a directional (one-tailed) Pearson's r test, with an alpha level of significance at 0.05.

Results

Participant Characteristics

There were 46 women in the study. The average age of the women was 42 years ($SD=7.6$; range, 28-55 years). The majority of the women ($N = 35$; 76.1%) were white; 15.2% were black and 8.7% were of other races.

Most of the women had a Bachelor's or Graduate degree ($N = 28$; 60.9%). Most women in the study were employed full time ($N = 35$; 76.1%). More than half of the women had been pregnant (60.9%). As shown in Table 1, twenty-one participants had received treatment for their leiomyomas (47.8%), including myomectomy, birth control, progesterone, uterine artery embolisms, and acupuncture.

Symptom Severity and Health-Related Quality of Life

The mean symptom severity score on the UFS-QOL was 59.3 (SD=19.9; range, 12.5-100). The mean health-related quality of life score for the UFS-QOL was 43.2 (SD=21.0; range, 4.31-86.2). The symptom severity and health-related quality of life scores were significantly correlated [$r = -0.68$ ($p < 0.01$)], thus supporting the hypothesis.

Single items, rated 0 to 10, in addition to the UFS-QOL, also measured symptom severity and health-related quality of life. The mean score of the single item that measured symptom severity was 7.1 (SD=2.1). The mean score of the single item that measured health-related quality of life was 6.1 (SD=2.2). These were not significantly correlated ($r = -0.14$). There was a significant correlation between the single item symptom severity score and the symptom severity score of the UFS-QOL ($r = 0.68$, $p < 0.01$). However, the single item and UFS-QOL scores that measured health-related quality of life were not significantly related ($r = 0.17$).

The researchers proceeded to examine the six subscales. The means of the six subscales, which ranged from 38.9 to 46.4, are listed in Table 2. There was a significant, negative correlation between symptom severity and each of the six subscales. (Table 3 shows these results).

Because the researchers were interested in the differences among women of color and white participants, symptom severity and the health-related quality of life on the UFS-QOL were analyzed for both groups. The mean symptom severity score on the UFS-QOL for women of color was 57.4 (SD=23.9) and 60.0 (SD=18.9) for the white participants. The mean health-related quality of life score for women of color on the UFS-QOL was 38.1 (SD=25.6), while the mean score for white participants was 45.1

(SD=19.4). The scores were not significantly different for women of color and white women.

Discussion

This study evaluated the symptom severity and health-related quality of life of women with uterine leiomyomas. The mean symptom severity scores on the UFS-QOL indicated that the participants had a moderate symptom severity. As a result, their mean health-related quality of life scores on the UFS-QOL were considerably reduced from what would be considered an average health-related quality of life. The correlations between these scores were negative and significant, thus supporting the hypothesis. These findings complement a study by Rannestad et al. (2000), which also found that the symptoms of women with various gynecological conditions have a negative impact on the quality of life. This study further supports the fact that women with gynecological conditions, including uterine leiomyomas have a considerably decreased quality of life.

Findings from a previous study by Salter (1985), implied that symptoms such as excessive bleeding and pain, that are experienced with various gynecological conditions, increase the risk of anxiety and depression of women with gynecological conditions. The results of this study suggest that women with uterine leiomyomas, who may experience pain and bleeding as well as bulk symptoms, are specifically at a risk as well. In the present study the participants' symptom severity was significantly correlated with all six domains. Thus, it can be construed that women with symptomatic leiomyomas are at risk for depression and anxiety because, according to the UFS-QOL, the more severe the participants' symptoms were, the more likely the participants felt hopeless, self-conscious about their appearance, or were less productive at work. Additionally, the more severe the

symptoms were, the more likely that the participants would avoid physical activity and sexual relations, which may lead to a decrease in self-esteem and relationship problems.

The symptom severity scores of the women of color indicated that they experienced less severe symptoms than white participants. However, the women of color health-related quality of life scores were lower on average, which suggests that they have a poorer quality of life than that of white participants. Still, there was no significant difference between the two groups for health-related quality of life or symptom severity. These findings are contradictory to those found by Kjerulff et al. (1996), which found that black women with leiomyomas had significantly worse symptom severity than white participants.

Implications for Research

In the present study, there were a limited number of African-American participants, so the researchers analyzed the differences in symptom severity and health-related quality of life of all women of color, which included African-American, Hispanic and Asian women. The literature suggests that African-American women have greater symptom severity than white women and other ethnic minorities (Kjerulff et al. 1996; Pron et al., 2003). The fact that there were a limited number of African-American participants in the study may explain why these results were not significant. Future research should recruit larger populations of African-Americans and other ethnic minorities to analyze potential racial differences in results on the UFS-QOL between them and white participants.

This study included women who had intact uteri, so women who have had hysterectomies were not included. Women with the worst symptom severity and the

poorest quality of life are more likely to receive hysterectomies to bring an end to their symptoms and improve their quality of life (Carlson et al., 1994), yet it is important to note that 46% (n=21) of the women in the study had some type of treatment for their leiomyomas. Thus, in future studies, researchers may consider having participants complete the UFS-QOL before and after any treatment for their leiomyomas to evaluate the effectiveness of the treatment.

Implications for Nursing

By using the UFS-QOL, a tool that analyzes symptoms unique to uterine leiomyomas, the researchers found that women who have symptomatic leiomyomas are at risk for having a poor quality of life. More specifically, the participants' symptom severity seemed to have the most impact on their activity levels. This finding along with those of Pron et al. (2003) implies that women with symptomatic uterine leiomyomas may not exercise, travel or do other activities as much as they would like. As a result, nurses should not only discuss management of physical symptoms with patients, but they should also be certain to assess the activity level of the client and implement interventions that will help the client to maintain an activity level that is desirable to the client. Furthermore, the results of this study suggest that the symptom severity of the participants had a damaging impact on their energy levels and self-consciousness. Engaging in physical activity is especially beneficial since it has been shown to improve mood, decrease fatigue and increase vigor (Lane & Lovejoy, 2001).

Practitioners may also consider using the UFS-QOL as an additional assessment to help guide decisions about a patient's plan of care. For instance, in this study, the participants' symptom severity negatively affected all six subscales of the health-related

quality of life on the UFS-QOL. Problems relating to subscales like concern and self-consciousness may be difficult for an individual to clearly express. Additionally, it is not likely that patients inform their practitioners about any emotional problems or a decrease in quality of life that they may be experiencing as a result of their leiomyoma symptoms. Subjective symptoms such as pain, discomfort and bloating are also difficult for a practitioner to assess. Therefore, practitioners may use this tool as a way to facilitate communication between the practitioner and patient in regards to physical and emotional concerns that affect the patient's quality of life.

Limitations

One of the limitations of this study was the small sample size. A larger sample size may have helped identify a stronger relationship between symptom severity and health-related quality of life.

Another major limitation of the study was that the single scaled items were stated in a way that may have altered the anticipated results. The items were the last two on the demographics page, and the researchers believe that the participants did not take note as to how the questions were arranged. In future studies, the items should be stated so the best and worst ratings are absolutely clear for symptom severity and health-related quality of life.

In conclusion, women with symptomatic leiomyomas are at risk for developing a poor health-related quality of life. Thus, it is important that nurses are aware of the common problems that accompany symptomatic leiomyomas in order to help women manage their physical symptoms and minimize their psychosocial distress, thus maximizing their quality of life.

Table 1

Treatment Types

<u>Treatment</u>	<u>N = 21</u>	<u>Percent</u>
Myomectomy	6	28.6
Birth Control	3	14.3
Uterine Artery Embolization	3	14.3
Complementary and Alternative Medicine	4	19.0
Multiple	4	19.0
<u>Medications</u>	<u>1</u>	<u>4.8</u>

Table 2

UFS-QOL Subscales

	Mean	Standard Deviation
Concern	41.2	29.0
Activity	44.3	23.6
Energy/Mood	46.4	26.2
Control	44.1	24.7
Self-Consciousness	38.9	29.1
<u>Sexual Function</u>	<u>40.2</u>	<u>29.1</u>

Table 3

Correlations between Symptom Severity and HRQL and Six Subscales

	HRQL	Concern	Activity	Energy	Controls	Self- Consciousness	Sex
Symptom							
Severity		-0.68**	-.054**	-0.69**	-0.59**	-0.47**	-0.43*

0.36*

* = $p < 0.05$, ** = $p < 0.01$

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